



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Sunil Chada *et al.*

Serial No.: 10/017,472

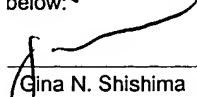
Filed: December 7, 2001

For: METHODS OF TREATMENT  
INVOLVING HUMAN MDA-7

Group Art Unit: 1632

Examiner: Qian J. Li

Atty. Dkt. No.: INGN:097US

CERTIFICATE OF MAILING 37 C.F.R. 1.8	
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March 23, 2004	
Date	Gina N. Shishima

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

MS DD  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R §§ 1.97(g), (h), this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be

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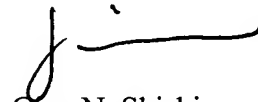
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construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

A fee as set forth in 37 C.F.R. § 1.17(p) in the amount of \$180.00 is enclosed herewith. If an appropriate check has not been enclosed, or if it is insufficient, the Commissioner is authorized to deduct the appropriate fee from Fulbright & Jaworski Account No.: 50-1212/INGN:097US

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



Gina N. Shishima  
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Attorney for Applicants

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Date: March 23, 2004



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**MS DD**

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RE: *U.S. Patent Application No. 10/017,472 entitled "METHODS OF TREATMENT INVOLVING HUMAN MDA-7" – Sunil Chada et al.*  
*Our reference: INGN:097US*

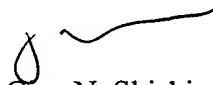
Sir:

Enclosed for filing in the above-referenced patent application is a Supplemental Information Disclosure Statement, Form PTO-1449, and references A25-A36, B9, and C78-C111.

A fee as set forth in 37 C.F.R. § 1.17(p) in the amount of \$180.00 is enclosed. If an appropriate check has not been enclosed, or if it is insufficient, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski L.L.P. Account No.: 50-1212/INGN:097US.

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Respectfully submitted,

  
Gina N. Shishima  
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GNS/kmv  
Encl.: as noted

Form PTO-1449 (modified)

Atty. Docket No.

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List of Patents and Publications for Applicant's

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U.S. Patent Documents

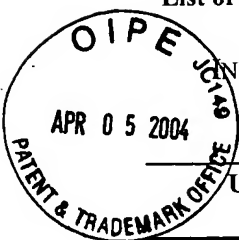
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Foreign Patent Documents

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## U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A25	2003/0066095	4/03/03	Baubet <i>et al.</i>	800	3	5/24/01
	A26	6,177,074	1-23-01	Glue <i>et al.</i>	424	85.7	3-30-99
	A27	6,204,022	3/20/01	Johnson <i>et al.</i>	435	69.51	10/20/97
	A28	6,207,145	3/27/01	Tovey	424	85.4	5/09/97
	A29	6,250,469	6/26/01	Kline	206	571	11/01/00
	A30	6,326,466	12/04/01	Bottaro and Petryshyn	530	324	7/29/97
	A31	6,331,525	12/18/01	Chiou and Carlo	514	44	8/23/99
	A32	6,342,379	1/29/02	Tsien and Gonzalez	435	173.4	12/13/99
	A33	6,348,352	2-19-02	Shepard <i>et al.</i>	435	455	12-04-95
	A34	6,350,589	2/26/02	Morris <i>et al.</i>	435	41	12/31/98
	A35	6,372,218	4/16/02	Cummins	424	184.1	1/31/95
	A36	6,379,701	4/30/02	Tracy <i>et al.</i>	424	486	9/18/00

## Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B9	WO 00/26368	5/11/00	PCT			

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C78	Co-pending U.S. Application No. 09/615,154.
	C79	Balachandran <i>et al.</i> , "Activation of the dsRNA-dependent protein kinase, PKR, induces apoptosis through FADD-mediated death signaling," <i>EMBO J.</i> , 17(23):6888-6902, 1998.

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Form PTO-1449 (modified)

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Exam. Init.	Ref. Des.	Citation
	C108	Toyoshima <i>et al.</i> , "p27, a novel inhibitor of G1 cyclin-Cdk protein kinase activity, is related to p21," <i>Cell</i> , 78: 67-74, 1994.
	C109	Tsuiki <i>et al.</i> , "Mechanism of hyperploid cell formation induced by microtubule inhibiting drug in glioma cell lines," <i>Oncogene</i> , 20: 420-429, 2001.
	C110	Wang <i>et al.</i> , "Interleukin 24 (MDA-7/MOB-5) signals through two heterodimeric receptors, IL-22R1/IL-20R2 and IL-20R1/IL-20R2," <i>J Biol Chem</i> , 277: 7341-7347, 2002.
	C111	Zamanian-Daryoush <i>et al.</i> , "Cell cycle regulation of the double stranded RNA activated protein kinase, PKR," <i>Oncogene</i> , 18(2): 315-326, 1999.

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Exam. Init.	Ref. Des.	Citation
	C80	Cuddihy <i>et al.</i> , "Double-stranded-RNA-activated protein kinase PKR enhances transcriptional activation by tumor suppressor p53," <i>Mol. Cell. Biol.</i> , 19(4):2475-2484, 1999.
	C81	Dagon <i>et al.</i> , "Double-stranded RNA-dependent protein kinase, PKR, down-regulates CDC2/cyclin B1 and induces apoptosis in non-transformed but not in v-mos transformed cells," <i>Oncogene</i> , 20(56):8045-8056, 2001.
	C82	Deb <i>et al.</i> , "RNA-dependent protein kinase PKR is required for activation of NF- $\kappa$ B by IFN- $\gamma$ in a STAT1-independent pathway," <i>J. Immunol.</i> , 166:6170-6180, 2001.
	C83	Dumoutier <i>et al.</i> , "Cutting edge: STAT activation by IL-19, IL-20 and mda-7 through IL-20 receptor complexes of two types," <i>J Immunol</i> , 167:3545-3549, 2001.
	C84	Eck and Wilson, "Gene-based therapy," <i>Goodman &amp; Gilman's The Pharmacological Basis of Therapeutics</i> , McGraw-Hill, 77-101, 1996.
	C85	Ellerhorst <i>et al.</i> , "Loss of MDA-7 expression with progression of melanoma" <i>J Clin Oncol</i> , 20:1069-1074, 2002.
	C86	Fickenscher <i>et al.</i> , "The interleukin-10 family of cytokines," <i>Trends Immunol</i> , 23: 89-96, 2002.
	C87	Gazdar and Minna, "Targeted therapies for killing tumor cells," <i>Proc. Natl. Acad. Sci., USA</i> , 98(18):10028-10030, 2001.
	C88	Gil <i>et al.</i> , "Induction of apoptosis by double-stranded-RNA-dependent protein kinase (PKR) involves the $\alpha$ subunit of eukaryotic translation initiation factor 2 and NF- $\kappa$ B," <i>Molecular and Cellular Biology</i> , 19(7):4653-4663, 1999.
	C89	Goh <i>et al.</i> , "The protein kinase PKR is required for p38 MAPK activation and the innate immune response to bacterial endotoxin," <i>EMBO J.</i> , 19(16):4292-4297, 2000.
	C90	Górecki, "Prospects and problems of gene therapy: an update," <i>Expert Opin. Emerging Drugs</i> , 6(2):187-198, 2001.
	C91	Haines <i>et al.</i> , "Expression of PKR (p68) recognized by the monoclonal antibody TJ4C4 in human lung neoplasms," <i>Virchows Arch. B. Cell Pathol.</i> , 62:151-158, 1992.
	C92	Huang <i>et al.</i> , "Genomic structure, chromosomal localization and expression profile of a novel melanoma differentiation associated (mda-7) gene with cancer specific growth suppressing and apoptosis inducing properties," <i>Oncogene</i> , 20:7051-7063, 2001.
	C93	Jagus <i>et al.</i> , "PKR, apoptosis and cancer," <i>Int. J. Biochem.</i> , 31: 123-138, 1999.

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	C94	Jiménez <i>et al.</i> , "Signals leading to apoptosis-dependent inhibition of neovascularization by thrombospondin-1," <i>Nat Med</i> , 6(1):41-48, 2000.
	C95	Joki <i>et al.</i> , "Continuous release of endostatin from microencapsulated engineered cells for tumor therapy," <i>Nat Biotech</i> , 19(1):35-39, 2001.
	C96	Kaye <i>et al.</i> , "A single amino acid substitution results in a retinoblastoma protein defective in phosphorylation and oncoprotein building," <i>Proc. Natl. Acad. Sci., USA</i> , 87:6922-6926, 1990.
	C97	Kim <i>et al.</i> , "Bid-induced cytochrome c release is mediated by a pathway independent of mitochondrial permeability transition pore and Bax," <i>J Biol Chem</i> , 275(50):39474-39481, 2000.
	C98	Madireddi <i>et al.</i> , "AP-1 and C/EBP transcription factors contribute to mda-7 gene promoter activity during human melanoma differentiation," <i>J Cell Physiol</i> , 185:36-46, 2000.
	C99	Maheshwari <i>et al.</i> , "Differential effects of interferon gamma and alpha on in vitro model of angiogenesis," <i>J Cell Physiol</i> , 146:164-169, 1991.
	C100	Pataer <i>et al.</i> , "Adenoviral Bak overexpression mediates caspase-dependent tumor killing," 60: 788-792, 2000.
	C101	Pataer <i>et al.</i> , "Adenoviral transfer of the melanoma differentiation-associated gene 7 (mda7) induces apoptosis of lung cancer cells via up-regulation of the double-stranded RNA-dependent protein kinase (PKR)," <i>Cancer Res</i> , 62:2239-2243, 2002.
	C102	Peng <i>et al.</i> , "Mitotic and G2 checkpoint control: regulation of 14-3-3 protein binding by phosphorylation of Cdc25C on serine-216," <i>Science</i> , 277:1501-1505, 1997.
	C103	Restifo <i>et al.</i> , "Hierarchy, tolerance, and dominance in the antitumor T-cell response," <i>J. Immunother.</i> , 24(3):193-194, 2001.
	C104	Rich <i>et al.</i> , "Cytokines: IL-20 - a new effector in skin inflammation," <i>Curr Biol</i> , 11:R531-534, 2001.
	C105	Saelens <i>et al.</i> , "Translation inhibition in apoptosis: caspase-dependent PKR activation and eIF2- $\alpha$ phosphorylation," <i>J. Biol. Chem.</i> , 276: 41620-41628, 2001.
	C106	Su <i>et al.</i> , "A combinatorial approach for selectively inducing programmed cell death in human pancreatic cancer cells," <i>Proc. Natl. Acad. Sci., USA</i> , 98(18):10332-10337, 2001.
	C107	Tait, "HLA class I expression on human cancer cells," <i>Human Immunology</i> , 61:158-165, 2000.

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